UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,795	07/19/2001	Masaaki Nomura	159-67	9649

7590 09/24/2002

Nixon & Vanderhye
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/24/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,795	NOMURA ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- Th MAILING DATE of this communication app ars on the cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *4-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Declaration and the Information Disclosure Statement, received by the Office on July 31, 2001 and January 15, 2002, respectively.

Claim Objections

Claims 4-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from another multiple dependant claim. See MPEP § 608.01(n). The examiner has treated the claims as though each dependant claim depends from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Us Patent 4,508,723 to Schaffner *et al.*. Schaffner *et al.* disclose applicant's claimed drug (see claim 1). Additionally, Schaffner *et al.* teach that the drug can be formulated into pharmaceutical dosage forms containing adjuncts, such as sucrose and mannitol (c 22, l 63-66). Schaffner *et al.* also teach that the formulation can be in the form of a syrup (c 8, l 44).

Claims 1-5, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,826,832 to Lang. Lang discloses penen compounds. More specifically, Lang teaches the pharmacologically acceptable compounds of the present invention ca n be used in many different types of formulations, and can be combined with additives, such as sucrose and mannitol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaffner *et al.* or Lang, as discussed above.. The references do not specifically disclose that the mannitol present be in the form of D-mannitol. However, it is the position of the examiner that the teachings of the references are drawn to the use of mannitol in general, and this is generic to the particular type of manntiol claimed by applicant. It is further the position of the examiner that, absent a showing of unexpected results, the choosing of a specific mannitol when given a teaching to mannitols in general would be routinely done by one of ordinary skill in the art. The results must be those that accure from the specific limitation.

The references also lack the teaching to the specific amount of sucrose employed in the composition. However, it is the position of the examiner that the determination of particular amounts of a known additive is within the skill of the ordinary worker as part of the process of

normal optimization. Therefore, this limitation does not render patentable distinction to the claims.

Additionally, the references do not disclose the process applicant has included in the instant product claims. However, according to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

References of Interest

EP 758 651 A1 to Inoue teaches applicant's drug in combination with mannitol in pharmaceutical compositions.

US Patent 4,540,689 to Muto teaches applicant's drug in combination with suitable carriers, diluents, or adjuvants, such as mannitol.

UK Application 2 124 614 A to Alpegiani teaches applicant's drug in combination with carriers, such as saccharose and mannitol. Alpegiani also teaches syrup formulations.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Amy E. Pulliam
Patent Examiner
Art Unit 1615

aep
September 23, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600